

FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (REV. 1094) TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER U0139/7001 <div style="font-size: 1.5em; font-weight: bold; text-align: center;">09/980971</div> <small>U.S. APPLICATION NO. (If known, see 37 CFR 1.5)</small> <div style="font-weight: bold; text-align: center;">JC18 Rec'd PCT/PTO 26 OCT 2001</div>
INTERNATIONAL APPLICATION NO. PCT/GB00/01725	INTERNATIONAL FILING DATE 05 May 2000 (05 05.00)	PRIORITY DATE CLAIMED 06 May 1999 (06.05.99)
TITLE OF INVENTION CARDIAC DEFIBRILLATION		
APPLICANT(S) FOR DO/EO/US ANDERSON, John McCune, EVANS, Noel		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This express request to begin national procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). <ol style="list-style-type: none"> a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 		
Items 11. To 16. Below concern document(s) or information included:		
<ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98 with references. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: <ul style="list-style-type: none"> Copy of page 1 of PCT Published Application Copy of International Search Report as Published Copy of International Preliminary Examination Report w/Annexes 		
Express Mail Label No. EL819465665US Mailed October 26, 2001		

U.S. APPLICATION NO. (If known, enter GPO 1-5)	INTERNATIONAL APPLICATION PCT/GB00/01725	ATTORNEY'S DOCKET NUMBER U0139/7001
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21. ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	\$1000.00
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	\$860.00
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but but international search fee paid to USPTO (37 CFR 1.445(a)(2)),paid to USPTO	\$710.00
International preliminary examination fee paid to USPTO (37 CFR 1.482) But all claims did not satisfy provisions of PCT Article 33(1)-(4)	\$690.00
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)	\$100.00

CALCULATIONS PTO USE ONLY

\$ 860 00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 X 30
Months from the earliest claimed priority date (37 CFR 1.492(e)).

	\$ 130 00
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CLAIMS	NUMBER FILED	NUMBER EXTRA
Total Claims	11- 20 =	0
Independent Claims	2- 3 =	0

MULTIPLE DEPENDENT CLAIM(S) (if applicable)	+ \$270.00
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\$ 270 00

TOTAL OF ABOVE CALCULATIONS

\$ 1260.00

☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.

\$ 1200.00
\$ 630.00

SUBTOTAL

	\$ 630.00
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Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
Months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE

\$ 630.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate coversheet (37 CFR 3.28, 3.31). \$40.00 per property

\$

TOTAL FEES ENCLOSED

\$ 630.00


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NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

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REGISTRATION NO



CUSTOMER NUMBER **23628**

1 Cardiac Defibrillation

2
3 This invention relates to cardiac defibrillation, and
4 in particular (but not exclusively) to an apparatus for
5 delivering an electrical defibrillating signal to a
6 human heart in the state of atrial fibrillation (AF),
7 using transdermal energy transfer to a passive
8 implanted device.

9
10 Atrial fibrillation is a common heart arrhythmia that
11 increases in prevalence with age, with typically 10% of
12 people over the age of 70 experiencing an incident.
13 The process of cardioversion of AF to normal sinus
14 rhythm (SR) has traditionally been attempted by
15 pharmacological measures or transthoracic direct
16 current shock. The former has been limited by variable
17 cardioversion rates and the risk of side effects, in
18 particular proarrhythmia. The latter requires sedation
19 or anaesthesia and high energy shocks, and there is a
20 high recurrence rate. For these reasons, there has
21 been interest in catheter-based transvenous atrial
22 defibrillation and its potential use in an implantable
23 atrial defibrillator. However, atrial implantable
24 defibrillators are complex devices requiring on-board
25 pattern recognition with complex recording and follow-

1 up procedures. The need for electrical charging
2 circuitry using active devices adds to the complexity
3 and weight of the implant.

4
5 The present invention provides an apparatus for cardiac
6 defibrillation which comprises an external circuit and
7 an implantable circuit; the external circuit including
8 an induction transmitting coil and signal generating
9 means for applying radio frequency pulses of
10 predetermined shape to the transmitting coil; the
11 implantable circuit including an induction receiving
12 coil for receiving pulses when the two coils are in
13 proximity, and a rectification circuit having an input
14 connected to the receiving coil and an output driving
15 electrodes implantable in the heart.

16
17 In a preferred form of the invention, for use in atrial
18 defibrillation, the power transmitted per pulse is less
19 than about 5J and the radio frequency is in the range
20 3-30 MHz, typically about 7MHz.

21
22 Most preferably, the implantable circuit contains only
23 passive components.

24
25 From another aspect the invention provides a method of
26 cardiac (preferably atrial) defibrillation which
27 comprises transmitting pulses of controlled shape and
28 energy transdermally by high frequency magnetic
29 induction to a substantially passive implanted circuit
30 which includes electrodes implanted in the heart.

31
32 It is known to transfer energy transdermally by
33 induction, but only for purposes of recharging
34 batteries in implanted devices such as pacemakers or
35 continuously powering implanted devices such as pumps.
36 It has not hitherto been proposed to use such

1 techniques to transfer controlled waveforms for high-
2 energy physiological stimulation.

3

4 An embodiment of the invention will now be described,
5 by way of example, with reference to the accompanying
6 drawings, in which:

7

8 Figure 1 shows the elements required for controlled,
9 transdermal energy delivery to a cardiac load;

10 Figure 2 illustrates the circuitry required external to
11 the body;

12 Figure 3 represents the body-internal circuitry; and

13 Figure 4 illustrates waveforms in the apparatus.

14

15 In the apparatus (Figure 1), an appropriately
16 synchronised trigger pulse is firstly generated, based
17 on the subject's electrocardiogram (ecg). This pulse,
18 after shaping in a pulse generation and shaping circuit
19 12 to a waveform 1 suitable for AF conversion, is used
20 to amplitude modulate a radio frequency (RF) carrier
21 generator 2 at a power level consistent with the
22 transmission of 1-5 J of energy to the internal load,
23 itself nominally 50 Ω resistive. The transmission path
24 takes the form of a pair of coaxially-aligned transmit
25 3 and receive 4 inductors constructed in the form of an
26 RF transformer. The diameters of the coils 3 and 4 are
27 set so as to optimise energy transfer at a physical
28 spacing not less than the thickness of the thoracic
29 wall 13. Both inductors are wound with enamelled
30 copper wire. The transmitting coil 3 is mounted on an
31 insulated paddle to facilitate adjustment in its
32 placement on the subject's body. The implanted
33 circuitry is mounted on a printed circuit board and
34 consists of the receiving coil 4 connected to impedance
35 matching, rectification and wave-shaping components 5.
36 The final defibrillating signal is connected to the

1 heart (indicated as an electrical load 6) by catheters
2 7, one placed in the lateral right atrium (RA) and the
3 other in the distal great cardiac vein via the coronary
4 sinus. Alternatively, any conventional atrial
5 defibrillation delivery system may be used.

6
7 In one example, the coils 3 and 4 are designed to give
8 optimum inductive coupling at a centre-to-centre
9 spacing of 20mm. Given a maximum diameter, for
10 practicability, of the receiving coil 4 of 35mm, the
11 transmitting coil 3 has a diameter of 53mm. Both
12 inductors are wound with 1.5mm enamelled copper wire.
13 The transmitting coil 3 is arranged as a solenoidal
14 coil, spaced at one turn. The receiving coil 4 is
15 pile-wound to conserve space in the final implant.

16
17 Both inductors in the apparatus are tuned to resonance
18 at the selected operating frequency of the system,
19 typically in the range 3-30 MHz. As seen in Fig. 2,
20 the transmitter uses series tuning by capacitor 9.
21 Fig. 2 also shows a 50 ohm feed 15 from the generator
22 2, giving an operational loaded Q of approximately 5.
23 Referring to Fig. 3, the receiving coil is parallel
24 tuned, with capacitive matching to the load 6 by means
25 of capacitors C1 and C2. A radio-frequency choke 11
26 provides a DC path for rectifier current.
27 Rectification and shaping is effected in circuit 16.

28
29 Optionally, as shown in Figure 1 a telemetry link 8 may
30 be incorporated to provide ecg monitoring and feedback-
31 derived, automatic tuning of the energy delivery
32 system. Such a link may also be powered from energy
33 delivered transdermally, by using a low-power transfer
34 to power up the telemetry link, or to charge an on-
35 board battery. Alternatively, the ecg could be
36 transmitted via the induction coils using a suspended

1 suitable for driving the cardiac load. Fig. 4d shows a
2 monophasic pulse 17 and a biphasic pulse 18 which can
3 be produced from the single pulse of Fig. 4a.

4

5 Although described above with particular reference to
6 atrial defibrillation, the invention could find use in
7 ventricular defibrillation. Here, though, the required
8 energy levels are much higher (typically about 15J).

9

10 It will be appreciated that one of the benefits of the
11 embodiment described is that the implanted hardware is
12 entirely passive and does not require any implanted
13 power source. However, the invention does not exclude
14 the possibility of some active components being
15 implanted, with a reduced requirement for an internal
16 source of power.

17

18

1 CLAIMS

2

3 1. An apparatus for cardiac defibrillation which
4 comprises an external circuit and an implantable
5 circuit; the external circuit including an induction
6 transmitting coil and signal generating means for
7 applying radio frequency pulses of predetermined shape
8 to the transmitting coil; the implantable circuit
9 including an induction receiving coil for receiving
10 pulses when the two coils are in proximity, and a
11 rectification circuit having an input connected to the
12 receiving coil and an output driving electrodes
13 implantable in the heart.

14

15 2. An apparatus according to claim 1, for use in
16 atrial defibrillation, in which the power transmitted
17 per pulse is less than about 5J and the radio frequency
18 is in the range 3-30 MHz, preferably about 7MHz.

19

20 3. An apparatus according to claim 1 or claim 2, in
21 which the signal generating means comprises a radio
22 frequency generator switched or gated under the control
23 of a pulse generation and shaping means which in turn
24 is responsive to an ecg synchronisation signal.

25

26 4. An apparatus according to claim 3, in which the ecg
27 synchronisation signal is provided via a telemetry
28 transmitter implanted in the patient.

29

30 5. An apparatus according to any preceding claim, in
31 which the external circuit further includes a telephony
32 link by which the ecg may be transmitted to, and/or the
33 apparatus controlled from, a remote location.

34

35 6. An apparatus according to any preceding claim, in
36 which the external and implantable circuits include

1 impedance matching components to achieve a high degree
2 of tuning.

3

4

5 7. An apparatus according to claim 6, in which the
6 inductive coupling is tuned to resonance.

7

8 8. An apparatus according to claim 8, in which the
9 inductive coupling is tuned to resonance by use of
10 series resonance in the external circuit and parallel
11 resonance in the implantable circuit.

12

13 9. An apparatus according to any preceding claim, in
14 which the implantable circuit contains only passive
15 components.

16

17 10. A method of cardiac defibrillation which comprises
18 transmitting pulses of controlled shape and energy
19 transdermally by high frequency magnetic induction to a
20 substantially passive implanted circuit which includes
21 electrodes implanted in the heart.

22

23 11. The method of claim 10, in which the electrodes
24 are implanted to provide atrial defibrillation.

25

26

PCT

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61N 1/378		(11) International Publication Number: WO 00/67843
A1		(43) International Publication Date: 16 November 2000 (16.11.00)
(21) International Application Number: PCT/GB00/01725		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KR, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 5 May 2000 (05.05.00)		
(30) Priority Data: 9910323.6 6 May 1999 (06.05.99) GB		
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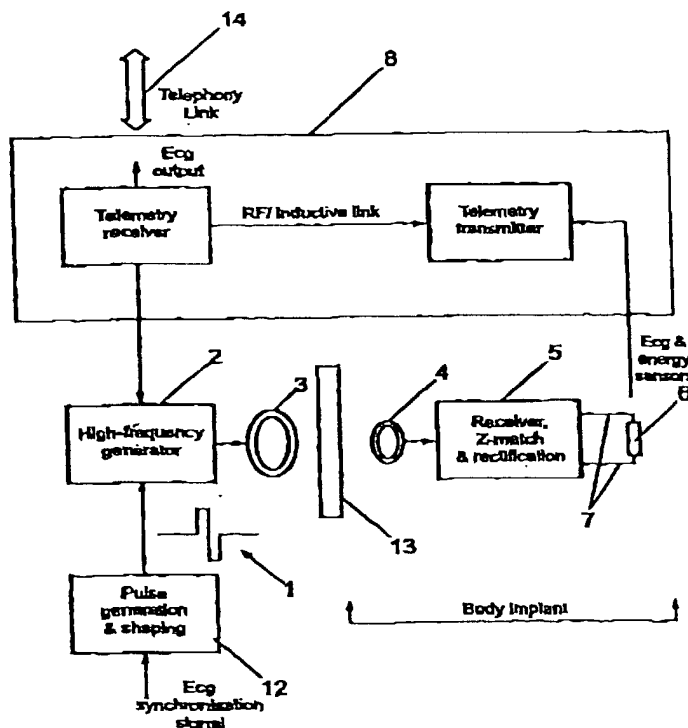
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CARDIAC DEFIBRILLATION

(57) Abstract

A defibrillator connected by catheters (7) to the heart (6) has an external circuit (2, 12) connected to a passive implanted circuit (5) by transdermal induction via coils (3, 4). For atrial defibrillation, pulses of 3-4J can be transmitted at about 7MHz without damage, using an implaned coil (4) of 20mm diameter.



1 / 3

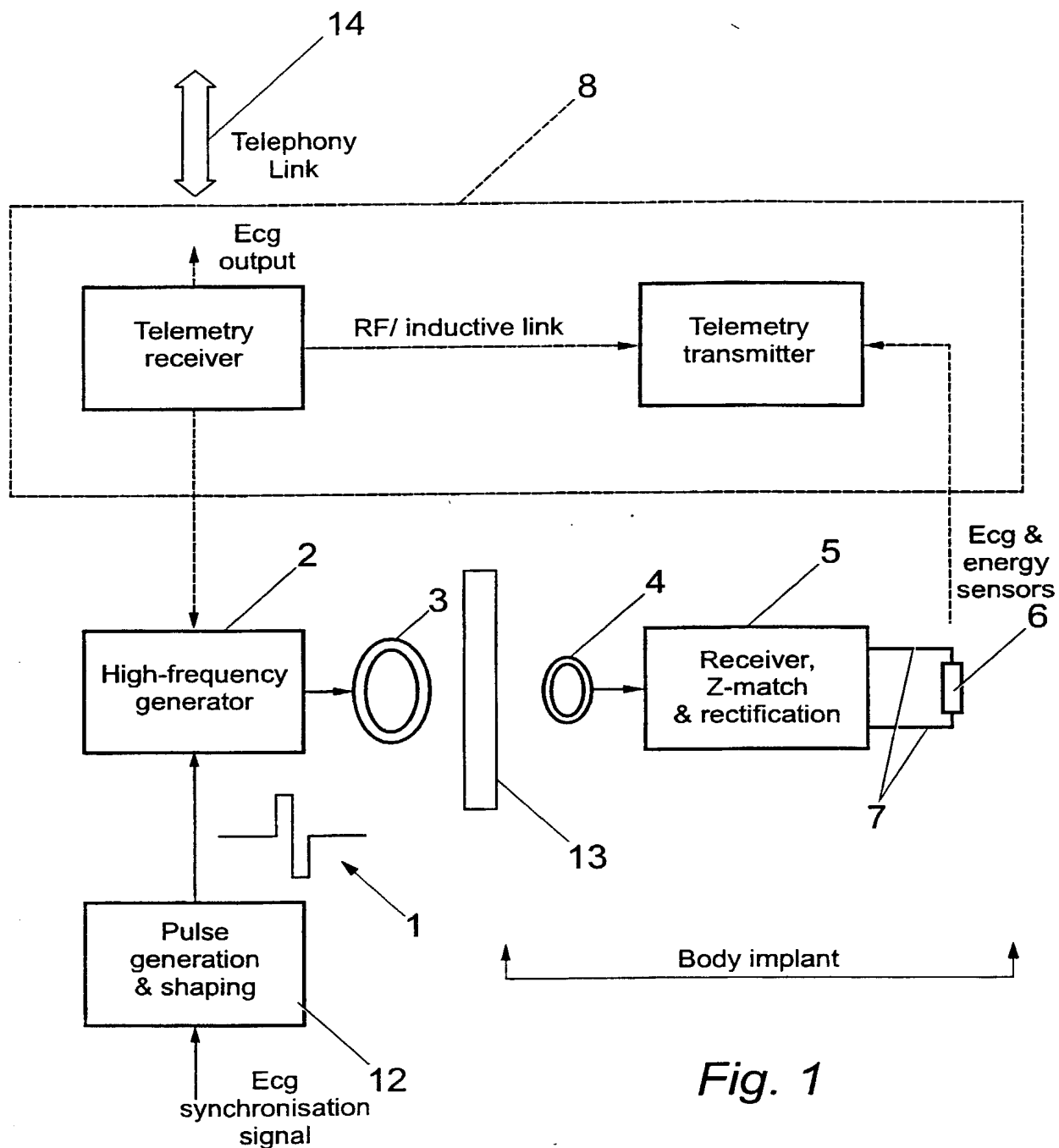


Fig. 1

2 / 3

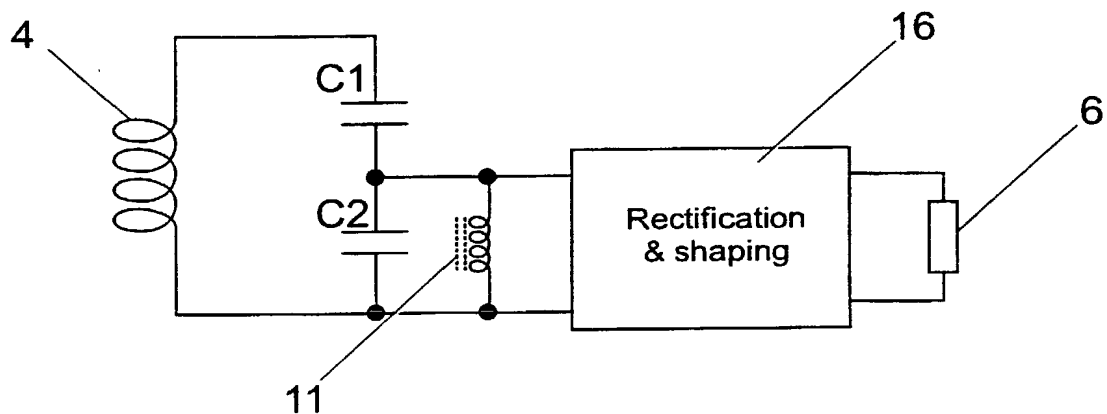
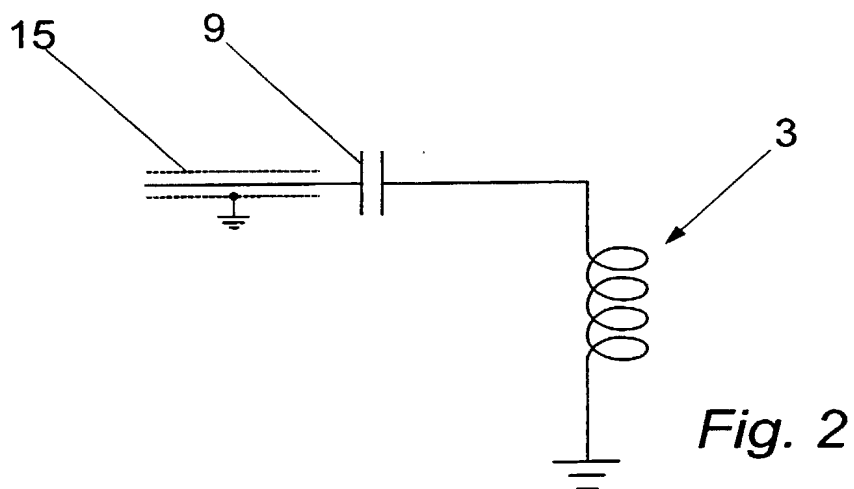
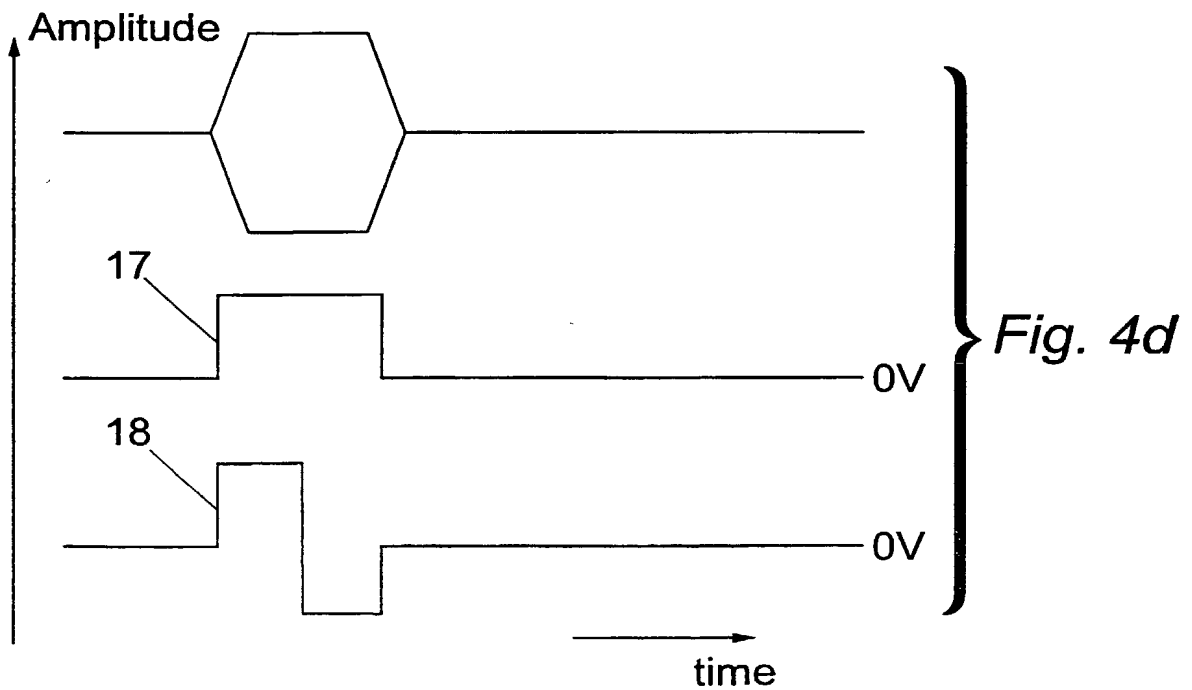
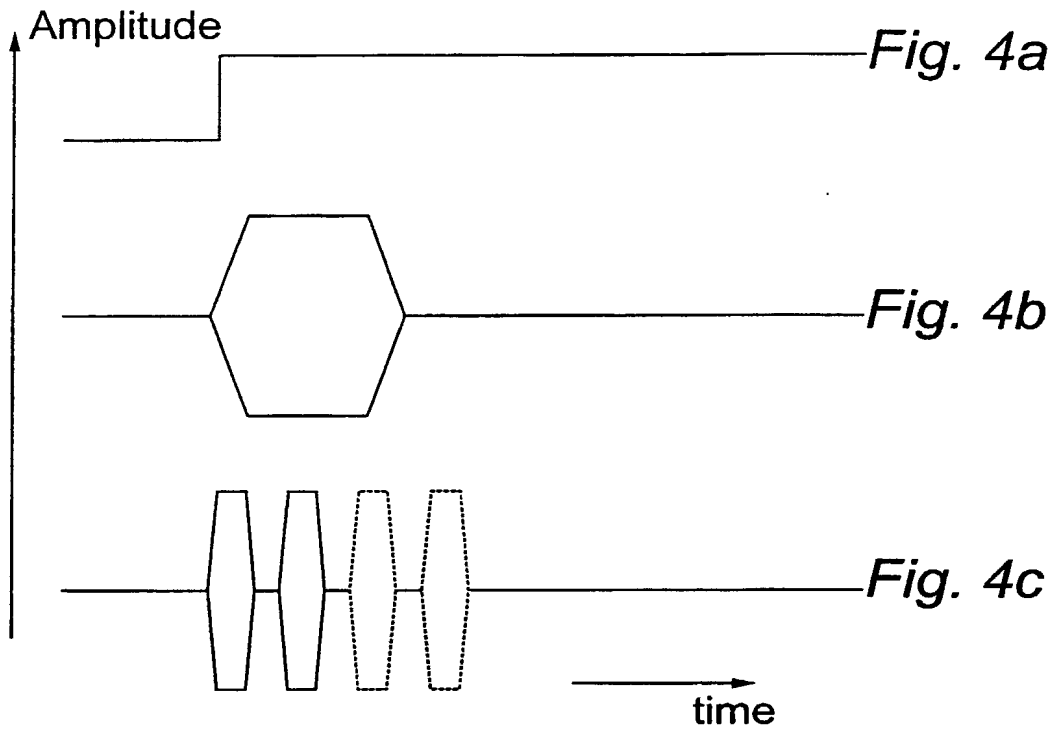


Fig. 3

3 / 3



Attorney Docket No. U0139/7001

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CARDIAC DEFIBRILLATION

the specification of which is attached hereto unless the following is checked:

☒ was filed on October 26, 2001, as U.S. Application No. 09/980,971, bearing attorney docket No. U0139/7001, and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or section 365(a) of any PCT International application designating at least one country other than the United States listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed:

Prior Foreign PCT International Application(s) and any priority claims under 35 U.S.C. §§119 and 365(a),(b):

			Priority Claimed	
<u>PCT/GB00/01725</u> (Number)	<u>PCT</u> (Country-if PCT, so indicate)	<u>05/05/2000</u> (DD/MM/YY Filed)	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
<u> </u> (Number)	<u> </u> (Country-if PCT, so indicate)	<u> </u> (DD/MM/YY Filed)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<u> </u> (Number)	<u> </u> (Country-if PCT, so indicate)	<u> </u> (DD/MM/YY Filed)	<input type="checkbox"/> YES	<input type="checkbox"/> NO

Docket No.: U0139/7001

Page 2

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)

(filing date)

(Application Number)

(filing date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or §365(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

PCT/GB00/01725

05/05/00

Published

(Application No.)

(filing date)

(status-patented, pending, abandoned)

PCT International Applications designating the United States:

(PCT Appl. No.)

(U.S. Ser. No.)

(PCT filing date)

(status-patented,pending,abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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Docket No.: U0139/7001

Page 3

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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